



**UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
087473, 789	06/07/95	CURTISS	MEGAN 100-21

18M1/1018

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EXAMINER	
HOUSEL, J	
ART UNIT	PAPER NUMBER
1802	8
10/18/96	

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on 7/17/96 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire _____ month(s), 30 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-35 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☐ Claims _____ are rejected.

5. ☐ Claims _____ are objected to.

6. ☒ Claims 1-35 are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

Art Unit:

DETAILED ACTION

Election/Restriction

1. In response to applicant's traversal of the restriction requirement set forth in Paper No. 4, mailed May 14, 1996, the following changes have been made to the restriction requirement. As a result of these changes, a new election is hereby required in response to this Office action. Any inconvenience caused by these modifications is regretted.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-29, drawn to an isolated microbial cell, classified in class 435, subclass 252.3.

II. Claims 30-35, drawn to a method of vaccination, classified in class 424, subclass 200.1.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product can be used in a diagnostic assay, in a process for selective insecticidal treatment, or in a process for evaluating environmental contamination with pollutants.

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It has been noted that applicants argue that the product cannot be restricted from the process of using since the product is not being restricted from the process of making under 37 CFR 1.141(b). However, the process of using the product in fact does not require the product of claim 1. Claim 1 is a cell having 2 genes, an essential gene and a lethal gene. Claim 30 uses a cell requiring only 1 gene, either an essential gene or a lethal gene. If claim 30 were amended to require both an essential gene and a lethal gene in accordance with claim 1, then the restriction between these two inventions would be withdrawn. Absent such an amendment, the restriction between the product and the process of use is deemed proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of claimed invention I:

Species A, claims 5 and 6, directed to a cell having a regulatory gene down regulating the lethal gene in a permissive environment.

Species B, claims 5 and 7, directed to a cell having a regulatory gene up regulating the lethal gene in a non-permissive environment.

Species C, claims 13 and 14, directed to a cell having a regulatory gene down regulating the essential gene in a non-permissive environment.

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Species D, claims 13 and 15, directed to a cell having regulatory gene up regulating the essential gene in a permissive environment.

Species E, claims 17 and 18, directed to a cell having a regulatory gene down regulating the replicative gene in a non-permissive environment.

Species F, claims 17 and 19, directed to a cell having a regulatory gene up regulating the replicative gene in a permissive environment.

Species G, claims 21, 22, 25 and 26, directed to a cell having an antigen expression gene.

These species are patentably distinct each from the other as each is clearly structurally and functionally different, requiring a divergent literature and patent search.

If applicant elects invention I, then applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-4, 8-12, 16, 20, 23, 24 and 27-29 generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations

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of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Housel whose telephone number is (703) 308-4027.

jch

October 15, 1996

James C. Housel
JCH
10/15/96
UNITED STATES PATENT EXAMINER
GROUP 100